Clinical Policy: Proton Pump Inhibitors

Reference Number: CP.CPA.209
Effective Date: 11.16.16
Last Review Date: 11.24
Line of Business: Commercial

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

The following are proton pump inhibitors (PPIs) requiring prior authorization: rabeprazole (AcipHex®, AcipHex® Sprinkle), dexlansoprazole (Dexilant®), esomeprazole (Nexium®, Nexium® 24HR, Nexium® 24HR ClearMinis™), omeprazole (Prilosec® Packets), lansoprazole (Prevacid® SoluTabs™), omeprazole/sodium bicarbonate (Konvomep™, Zegerid®, Zegerid® OTC).

FDA Approved Indication(s)

Indication	Aciphex	Aciphex Sprinkle	Dexilant	Nexium	Prilosec	Prevacid	Konvomep, Zegerid	ES
Duodenal ulcers	X			*	X	X	X†	
Duodenal ulcers, maintenance					*	X		
Duodenal ulcers, giant					*			
Erosive esophagitis	X		X^	X^	X^	X^	X†	X
Erosive esophagitis, Maintenance	X		X^	X	X^	X	X†	X
Gastric ulcers	*				X	X	X	
Nonsteroidal anti-inflammatory drug (NSAID)-associated gastric ulcer, risk reduction	*			X	*	X		X
NSAID-associated gastric ulcer, healing of				*	*	X		
Helicobacter pylori (*H. pylori*) Triple Therapy	X			X	X	X		X
H. pylori Dual Therapy					X	X		
H. pylori Quadruple therapy	*			*	*	*		
Pathological hypersecretory conditions, including Zollinger-Ellison Syndrome	X			X	X	X		X
Symptomatic gastroesophageal reflux disease (GERD) (erosive/ulcerative)	X	Xp		X^	X^	X^	X†	X

Indication	Aciphex	Aciphex Sprinkle	Dexilant	Nexium	Prilosec	Prevacid	Konvomep, Zegerid	ES
Symptomatic GERD, maintenance (erosive/ulcerative)	X							
Symptomatic GERD (non-erosive)	X^		X^	X		X^		X
Indigestion	*			*	*			
Drug-induced gastrointestinal (GI) disturbance					*			
Esophageal stricture					*			
Heartburn			X^	X^		*		
Reduction of risk of upper GI bleed in critically ill patients					*	*	X	

*****Clinical trials have demonstrated the efficacy and safety for these indications, although not currently FDA-approved.*
^ *Includes adults and pediatrics*
[P] *Pediatrics only*
[†] *Zegerid only*

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Aciphex/Aciphex Sprinkle, Dexilant, Konvomep, Nexium/Nexium 24HR/Nexium 24HR ClearMinis, Prilosec Packets, Prevacid SoluTabs, and Zegerid/Zegerid OTC are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. All Indications (must meet all)**:**

1. Prescribed for one of the following uses (a, b, c, d, e, or f):
   a. Symptomatic GERD, including heartburn or laryngopharyngeal reflux;
   b. Esophageal complications of GERD (e.g., erosive esophagitis, esophageal stricture, Barrett's esophagus, and Schatzki's ring);
   c. Extra-esophageal complications (e.g., laryngopharyngeal reflux, vocal cord damage/nodules, asthma, laryngitis, and pharyngitis);
   d. Peptic ulcer disease (e.g., gastric ulcers, duodenal ulcers, *H. pylori* and Zollinger-Ellison syndrome);
   e. Gastrointestinal bleed prophylaxis for NSAID use and member meets at least one of the following (i, ii, or iii):
      i. History of peptic ulcer disease;
      ii. Age ≥ 60 years;
      iii. Concurrent therapy with anticoagulants (e.g., warfarin, aspirin, clopidogrel) or oral corticosteroids (e.g., prednisone);
   f. Reduction of risk of upper gastrointestinal bleed in critically ill patients and request is for Konvomep or Zegerid oral suspension;
2. For lansoprazole disintegrating tablets or AcipHex Sprinkle: age ≥ 1 year old;

3. Member meets any of the following (a, b, c, d, or e):
   a. Age < 12 years and request is for lansoprazole disintegrating tablets, AcipHex Sprinkle, or Prilosec packets;
   b. Presence of G-tube or significant dysphagia and request is for Prevacid SoluTabs, Prilosec packets, or omeprazole/sodium bicarbonate: Failure of a ≥ 4-week trial of omeprazole and lansoprazole capsules, at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced (chart note documentation may be required);
   c. Currently on clopidogrel and request is for Dexilant, both of the following (i and ii):
      i. Failure of a ≥ 4-week trial of pantoprazole tablets, at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
      ii. Member must use generic dexlansoprazole, unless contraindicated or clinically significant adverse effects are experienced;
   d. Request is for esomeprazole, lansoprazole disintegrating tablets, omeprazole suspension, omeprazole/sodium bicarbonate, or rabeprazole: Failure of a ≥ 4-week trial of ALL of the following preferred generic PPIs at up to maximally indicated doses, unless all are contraindicated or clinically significant adverse effects are experienced: omeprazole capsules, pantoprazole tablets, and lansoprazole capsules;
   e. Request is for Dexilant, both of the following (i and ii):
      i. Failure of a ≥ 4-week trial of ALL of the following preferred generic PPIs at up to maximally indicated doses, unless all are contraindicated or clinically significant adverse effects are experienced: omeprazole capsules, pantoprazole tablets, and lansoprazole capsules;
      ii. Member failed, had intolerance, or is contraindicated to omeprazole capsules, pantoprazole tablets, and lansoprazole capsules: Member must use generic dexlansoprazole, unless contraindicated or clinically significant adverse effects are experienced;
4. For BID dosing requests of non-preferred agents for conditions other than *H. pylori* or pathological hypersecretory conditions, including Zollinger-Ellison syndrome: Member must be titrated up from once daily dosing;
5. Dose does not exceed the FDA-approved maximum recommended dose (refer to Section V).

Approval duration: 12 months or duration of request, whichever is less

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial; or

b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy;
3. If request is for Dexilant, member must use generic dexlansoprazole, unless contraindicated or clinically significant adverse effects are experienced;
4. If request is for a dose increase, new dose does not exceed the FDA-approved maximum recommended dose (refer to Section V).

Approval duration: 12 months or duration of request, whichever is less

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

EE: erosive esophagitis FDA: Food and Drug Administration

GERD: gastroesophageal reflux disease
GI: gastrointestinal
H. pylori: *Helicobacter pylori*
NSAID: non-steroidal anti-inflammatory drug
PPI: proton pump inhibitor

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
pantoprazole tablets and suspension (Protonix)	**Short-term treatment of erosive esophagitis associated with GERD** Adult and pediatric (age ≥ 5 years and weight ≥ 40 kg): 40 mg PO QD Pediatric (age ≥ 5 years and weight ≥ 15 kg to < 40 kg): 20 mg PO QD **Maintenance of healing of erosive esophagitis** 40 mg PO QD **Pathological hypersecretory conditions, including Zollinger-Ellison Syndrome** 40 mg PO BID	40 mg/day (240 mg/day for pathological hypersecretory conditions)
omeprazole capsules (Prilosec)	**Duodenal ulcer** 20 mg PO QD **Symptomatic GERD; Erosive esophagitis (treatment and maintenance)** Adult: 20 mg PO QD Pediatric (age 1 to 16 years): Weight 5 kg to < 10 kg: 5 mg Weight 10 kg to < 20 kg: 10 mg Weight ≥ 20 kg: 20 mg Pediatric (age 1 month to < 1 year): Weight 5 kg to < 10 kg: 5 mg Weight ≥ 10 kg: 10 mg ***H. pylori*** Triple therapy: 20 mg PO BID for 10 days, in combination with amoxicillin and clarithromycin Dual therapy: 40 mg PO QD for 14 days, in combination with clarithromycin 40 mg/day **Gastric ulcer** 40 mg PO QD	40 mg/day (360 mg/day for pathological hypersecretory conditions)

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Pathological hypersecretory conditions, including Zollinger-Ellison syndrome 60 mg PO QD to 80 mg/day PO in divided doses	
lansoprazole capsules (Prevacid)	**Duodenal ulcers, risk reduction of NSAID-associated gastric ulcer, maintenance of healing of erosive esophagitis** 15 mg PO QD **Short-term treatment of symptomatic GERD and erosive esophagitis** Adult: 15 to 30 mg PO QD Pediatric (age 1 to 11 years): Weight > 30 kg: 30 mg PO QD Weight ≤ 30 kg: 15 mg PO QD Pediatric (age 12 to 17 years): Non-erosive GERD: 15 mg Erosive esophagitis: 30 mg ***H. pylori*** Triple therapy: 30 mg PO BID for 10 or 14 days in combination with amoxicillin and clarithromycin Dual therapy: 30 mg PO TID for 14 days in combination with amoxicillin **Benign gastric ulcer, healing of NSAID-associated gastric ulcer** 30 mg PO QD **Pathological hypersecretory conditions, including Zollinger-Ellison syndrome** 60 mg PO QD	30 mg/day (180 mg/day for pathological hypersecretory conditions)

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): hypersensitivity (e.g., to drug or other PPIs, substituted benzimidazoles, or to any components of the formulation), coadministration with rilpivirine-containing products
- Boxed warning(s): none reported

Appendix D: General Information

- Dexilant 60 mg vs. Prevacid 30 mg in EE was evaluated in two studies. Non-inferiority was demonstrated in both studies, but superiority was demonstrated in only one study.

- Dexilant 90 mg was studied and did not provide additional clinical benefit over Dexilant 60 mg in EE.
- Over 90% of gastric and duodenal ulcers heal within 8 weeks of PPI therapy.
- Patients with PUD (DU or GU) should be tested for H. pylori and treated, if positive.
- For Laryngopharyngeal reflux (LPR), the American Academy of Otolaryngology recommends twice-daily dosing with PPIs for a minimum period of 6 months with the possibility of chronic treatment. BID dosing of PPIs has been shown to be superior to QD dosing in LPR.
- Two capsules of Zegerid 20 mg are not interchangeable with one capsule of Zegerid 40 mg because each capsule or packet contains the same amount of sodium bicarbonate.
- Pediatric patients: The safety and efficacy of Konvomep, Zegerid, and Protonix in children have not been established. The safety and efficacy of Dexilant have been established in pediatric patients 12 years of age and older. The safety and efficacy of Prevacid have been established in pediatric patients 1 to 17 years of age. The safety and efficacy of omeprazole have been established in pediatric patients 1 to 16 years of age. The safety and efficacy of Nexium have been established in pediatric patients 1 to 17 years of age for up to 8 weeks. The safety and efficacy of Aciphex have been established in pediatric patients 1 year and older for up to 36 weeks.
- Safety and efficacy of proton pump inhibitors have not been established in patients less than 1 year of age. Lansoprazole was no more effective than placebo in patients 1 month to less than 1 year of age with symptomatic GERD in a multi-center, double-blind, placebo controlled study (Orenstein et al, 2009). Studies with Aciphex Sprinkle do not support its use for the treatment of GERD in pediatric patients younger than 1 year of age.
- Prevacid has a non FDA-approved, Class IIa strength recommendation for H. pylori quadruple therapy per Micromedex.
- Aciphex has a non FDA-approved, Class IIa strength recommendation for H. pylori quadruple therapy and indigestion per Micromedex, and a Class IIb strength recommendation for gastric ulcer.
- According to their respective package inserts, concomitant administration of either pantoprazole or dexlansoprazole with clopidogrel in healthy subjects had no clinically important effect on exposure to the active metabolite of clopidogrel or clopidogrel-induced platelet inhibition. No dose adjustment of clopidogrel is necessary when administered with an approved dose of Protonix or Dexilant. American Hospital Formulary Service Drug Information further states, "If concomitant proton-pump inhibitor therapy [with clopidogrel] is considered necessary, some clinicians suggest the use of pantoprazole, which appears to be the weakest inhibitor of cytochrome P450 2C19 (CYP2C19) among proton-pump inhibitors."

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
rabeprazole (Aciphex)	Duodenal ulcers; Erosive esophagitis; *H. pylori* triple therapy; Symptomatic GERD (erosive/ulcerative), healing and maintenance;	20 mg PO QD (BID for *H. pylori*) (treatment duration varies)	20 mg/day (40 mg/day for *H. pylori*)

Drug Name	Indication	Dosing Regimen	Maximum Dose
	Pathological hypersecretory conditions, including Zollinger-Ellison syndrome	60 mg PO QD to 60 mg PO BID	120 mg/day
rabeprazole sodium delayed-release (Aciphex Sprinkle)	Symptomatic GERD (erosive/ulcerative)	**Pediatric** Age 1 to 11 years: Weight < 15 kg: 5 to 10 mg PO QD Weight ≥ 15 kg: 10 mg PO QD	10 mg/day
dexlansoprazole (Dexilant)	Healing of erosive esophagitis	60 mg PO QD	60 mg/day
	Maintenance of healed erosive esophagitis and relief of heartburn; Symptomatic non-erosive GERD	30 mg PO QD	30 mg/day
esomeprazole (Nexium, Nexium 24HR, Nexium 24HR Clear Minis)	GERD (including erosive esophagitis, symptomatic GERD)	**Adult** 20 to 40 mg PO QD to BID **Pediatric** Age 1 to 11 years: 10 to 20 mg PO QD Age 12 to 17 years: 20 to 40 mg PO QD Age 1 month to < 1 year: Weight 3 kg to 5 kg: 2.5 mg PO QD Weight > 5 kg to 7.5 kg: 5 mg PO QD Weight > 7.5 kg to 12 kg: 10 mg PO QD	80 mg/day
	Risk reduction of NSAID-associated gastric ulcer	20 mg to 40 mg PO QD	40 mg/day
	H. pylori triple therapy	40 mg PO QD for 10 days, in combination with amoxicillin and clarithromycin	40 mg/day
	Pathological hypersecretory conditions, including Zollinger-Ellison Syndrome	40 mg PO BID	240 mg/day

Drug Name	Indication	Dosing Regimen	Maximum Dose
omeprazole (Prilosec Packets)	Duodenal ulcer	20 mg PO QD	20 mg/day
	Symptomatic GERD; Erosive esophagitis (treatment and maintenance)	**Adult** 20 mg PO QD **Pediatric** Age 1 to 16 years Weight 5 kg to < 10 kg: 5 mg PO QD Weight 10 kg to < 20 kg: 10 mg PO QD Weight ≥ 20 kg: 20 mg QD Age 1 month to < 1 year (for EE only) Weight 3 kg to < 5 kg: 2.5 mg PO QD Weight 5 kg to < 10 kg: 5 mg PO QD Weight ≥ 10 kg: 10 mg PO QD	20 mg/day
	H. pylori	Triple therapy: 20 mg PO BID for 10 days, in combination with amoxicillin and clarithromycin Dual therapy: 40 mg PO QD for 14 days, in combination with clarithromycin	40 mg/day
	Gastric ulcer	40 mg PO QD	40 mg/day
	Pathological hypersecretory conditions, including Zollinger-Ellison Syndrome	60 mg PO QD to 80 mg/day PO in divided doses	360 mg/day
lansoprazole (Prevacid SoluTab)	Duodenal ulcers	15 mg PO QD	90 mg/day
	H. pylori	Triple therapy: 30 mg PO BID for 10 to 14 days, in combination with amoxicillin and clarithromycin Dual therapy: 30 mg PO TID for 14 days,	90 mg/day

Drug Name	Indication	Dosing Regimen	Maximum Dose
		in combination with amoxicillin	
	Gastric ulcer (including benign and healing of NSAID-associated gastric ulcers); Treatment of erosive esophagitis	**Adult** 30 mg PO QD (treatment duration varies) **Pediatric for EE** Age 1-11 years Weight ≤ 30 kg: 15 mg PO QD Weight > 30 kg: 30 mg PO QD Age 12-17 years 30 mg PO QD	30 mg/day
	Risk reduction of NSAID-associated gastric ulcers; Symptomatic GERD; Maintenance of healing of erosive esophagitis	15 mg PO QD (treatment duration varies) **Pediatric for GERD** Age 1-11 years Weight ≤ 30 kg: 15 mg PO QD Weight > 30 kg: 30 mg PO QD Age 12-17 years 15 mg PO QD	30 mg/day
	Pathological hypersecretory conditions, including Zollinger-Ellison Syndrome	60 mg PO QD to 90 mg/day PO BID	180 mg/day
omeprazole/ sodium bicarbonate (Konvomep)	Benign gastric ulcer	40 mg PO QD for 4 to 8 weeks	40 mg/day
	Reduction of risk of upper GI bleeding in critically ill patients	40 mg PO initially, followed by 40 mg PO 6 to 8 hours later, then 40 mg PO QD for 14 days	40 mg/day
omeprazole/ sodium bicarbonate (Zegerid, Zegerid OTC)	Duodenal ulcer; Symptomatic GERD; Erosive esophagitis (treatment and maintenance)	20 mg PO QD (treatment duration varies)	40 mg/day
	Benign gastric ulcer	40 mg PO QD	40 mg/day

Drug Name	Indication	Dosing Regimen	Maximum Dose
	Reduction of risk of upper GI bleeding in critically ill patients	40 mg oral suspension only: 40 mg PO initially, followed by 40 mg PO 6 to 8 hours later, then 40 mg PO QD for 14 days	40 mg/day

VI. Product Availability

Drug Name	Availability
rabeprazole (Aciphex)	Tablets, delayed-release: 20 mg
rabeprazole (Aciphex Sprinkle)	Capsules, delayed-release: 5 mg, 10 mg
dexlansoprazole (Dexilant)	Capsules, delayed-release: 30 mg, 60 mg
esomeprazole (Nexium)	• Capsules, delayed-release: 20 mg, 40 mg • Packets, powder for delayed-release oral suspension: 2.5 mg, 5 mg, 10 mg, 20 mg, 40 mg
lansoprazole (Prevacid Solutabs)	Tablets, delayed-release orally disintegrating: 15 mg, 30 mg
omeprazole (Prilosec Packets)	Packets, powder for delayed-release oral suspension: 2.5 mg, 10 mg
omeprazole/sodium bicarbonate (Konvomep)	Oral suspension: 2 mg/84 mg/mL after reconstitution in 90 mL, 150 mL, or 300 mL bottles
omeprazole/sodium bicarbonate (Zegerid)	• Capsules: 20 mg/1,100 mg, 40 mg/1,100 mg • Unit-dose packets for oral suspension: 20 mg/1,680 mg, 40 mg/1,680 mg
Available OTC products	
omeprazole/sodium bicarbonate (Zegerid OTC)	Capsules: 20 mg/1,100 mg
esomeprazole (Nexium 24HR)	Tablets, delayed-release: 20 mg
esomeprazole (Nexium 24HR ClearMinis)	Capsules, delayed-release: 20 mg

VII. References

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Prescribing Information

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q20 annual review: no significant changes; references reviewed and updated.	08.14.20	11.20
4Q 2021 annual review: revised redirection from Protonix packet to omeprazole and lansoprazole capsules for Prevacid SoluTabs, Prilosec packets, or omeprazole/sodium bicarbonate; references reviewed and updated.	08.09.21	11.21
Revised approval duration for Commercial line of business from length of benefit to 12 months or duration of request, whichever is less	01.20.22	05.22
4Q 2022 annual review: no significant changes; added coverage criteria for Zegerid oral suspension for gastrointestinal bleed reduction risk in critically ill patients that mirrors the FDA-approved indication language and which was already an existing covered indication within this policy; for Dexilant added generic redirection; references reviewed and updated. Template changes applied to other diagnoses/indications and continued therapy section. RT4: added Konvomep as a newly approved alternative dose form of an existing agent (Zegerid).	08.27.22	11.22
4Q 2023 annual review: no significant changes; references reviewed and updated.	08.22.23	11.23
4Q 2024 annual review: removed esomeprazole strontium as product is discontinued; references reviewed and updated.	07.11.24	11.24

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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